

## REMARKS

Claims 1-3, 5, 7-12, 14-22 and 27-38 are pending (new claim 38 being added, and claim 23 being cancelled by this amendment). Applicants note with appreciation the indication that claims 14-23, and 27-31, 32 and 35-37 are allowed, and claims 22 and 23 would be allowable if rewritten in independent form including all limitations of the base and intervening claims.

In the aforesaid Office Action, prosecution on the merits of the application was reopened on claims 1-3, 5, 7-12, 21-23, 33 and 34.

The Examiner rejected claims 1-3 and 9 under 35 USC 102(b) as being anticipated by Sun et al. (US 5,728,748), and claims 10-12 under 35 USC 103(a) as being unpatentable over Sun et al. alone, and claims 5, 7, 8 and 21 under 35 USC 103(a) as being unpatentable over Sun et al. in view of Chen et al. (US 5,849,846) and claims 33 and 34 under 35 USC 103(a) as being unpatentable over Sun et al. in view of Chen and Lee et al., stating that Sun et al. teaches a method of sterilizing a medical device including a purging step which occurs prior to forming the device wherein a container holding the polymer resin powder may be evacuated and an inert gas is used to then flush the container, and the resin then formed into an implant in an inert atmosphere, and the implant placed into an airtight container in an oxidant-free atmosphere for e-beam sterilization.

However, as stated by the Examiner, in Sun et al. the purging step occurs prior to forming the device. Therefore, Sun et al. does not disclose or suggest purging air which is present within an inner chamber or lumen of the medical device after formation of the

medical device, as required by amended claim 1 (or within an interior of balloon catheter as required by amended claim 33). Rather, Sun et al. discloses that air or moisture in the resin powder microstructure or deposited on the resin powder must be removed prior to forming the device specifically because it can't be removed by purging procedures after forming the device (in order to ensure that it will not be present on the device during subsequent sterilization in an oxygen-reduced atmosphere). Sun et al. does not disclose or suggest that, after forming the medical device, air which is allowed to be present within an inner chamber or lumen/interior of the device is removed prior to placing the device within the sterilization container or prior to purging the sterilization container. Sun et al. further discloses that, because the formation steps themselves can result in oxidation, the resin may be formed into stock and machined to form the medical device in an inert atmosphere (and annealed to prevent oxidation of the machined medical device upon subsequent exposure to oxygen). However, carrying out the formation steps in an inert atmosphere does not disclose or suggest the purging of air allowed to enter the interior of the already formed medical device prior to placing the device within the sterilization container or prior to purging the sterilization container.

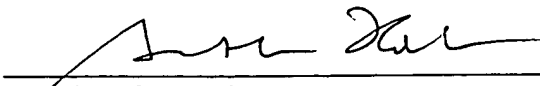
Applicants have amended claim 21 to include all the limitations of allowable claim 23.

New claim 38 corresponds substantially to allowed claim 27 except that claim 38 requires that the balloon was sterilized in an evacuated or inert gas-filled environment rather than in an evacuated or inert gas-filled container.

In light of the above amendments and remarks, applicant respectfully requests  
that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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